

### **REMARKS/ARGUMENTS**

In view of the amendments made to the claims and in view of the following remarks, reconsideration of the application is respectfully requested.

In the outstanding Office Action, various objections have been made to the claims, claim 14 has been rejected for formal reasons and all of the previously submitted claims have been rejected under anticipatory references. By the present amendment, the prior presented claims have been canceled and new claims 55-65 are presented for full consideration by the Examiner. In general, these claims have been presented to more particularly point out and distinctly claim the invention in view of the known prior art as will be detailed below.

Independent claim 55 as presented in the amendment/response relates to an apparatus for positioning and cementing a component of or for a prosthesis in a cavity or bore in a bone of a human or animal body. The apparatus comprises a tool having an elongated body and an end portion to which the component to be positioned and cemented is releasably mounted. In this way, the tool can retain the component for mounting in the cavity or bore in a bone, with the tool being maneuverable in order to properly position the component associated with the prosthesis. The tool also has means for delivering cement in order to secure the component. The cement delivery means is specifically stated to include a passage that extends through the elongated body, as well as an orifice at the end portion. The tool is configured to enable injecting of cement into a cavity or bore of a bone while still having the component mounted thereto. Furthermore, the tool includes an inflatable sealing element that is arranged proximate the end portion. Finally, the apparatus includes a means for inflating the sealing element in order to enable sealing of the cavity or bore in the bone for pressurization of the injected cement.

As the tool includes an end portion to which a prosthesis component is releasably mountable and further has an inflatable seal proximate the end portion, placement of the component in a cavity or bore in a bone, sealing of the cavity or bore and injecting the cement can all be performed by simply conveying the tool into the cavity or bore and controlling it from a position remote from the cavity or bore. In this manner, the component can be fixed in the body without requiring significant access to the area of implant which would otherwise be necessary to manipulate instruments and prosthesis components. Once the component has been cemented in place, the seal can be deflated, the component released from the tool and the entire tool simply withdrawn from the body.

The tool is particularly advantageous in connection with minimal invasive procedures. For example, the tool can be inserted through a relatively small bore in a femur while carrying a prosthesis component, such as a hip socket, establish the desired seal, deliver the cement to the requisite location and maintain the hip socket component in a desired position until the cement has at least partially cured. Based on the above, it should be readily apparent that the invention enables a component to be mounted to a body without requiring significant access to the particular joint or other bone region. Minimizing the invasive nature of such a procedure advantageously enables an operation to be performed in a manner that significantly reduces the recovery time of the patient.

Claim 60 is directed to similar structure as claim 55, with the claim specifying a tool having a cement delivery means and an annular sealing element. Of particular interest with respect to claim 60 is the use of an annular sealing element projecting forwardly from an end surface of the tool and spaced radially outward of component mounting structure. This configuration is considered to be particularly advantageous by enabling the tool to seal and cement the component in a cavity or bore of a bone by simply pushing the tool against the body.

With respect to independent claim 64, the tool portion of the apparatus is specifically stated to include a head to which a prosthesis component is releasably mountable. The tool also includes a first passage from which air is withdrawn to hold the component to the tool by suction. The tool also comprises a second passage for delivering cement to the tool head in order to cement the component in a cavity or bore. As the tool of the present invention is able to mount the component by suction, the component can be easily released from the tool from a position remote from the region into which the component is to be implanted. Therefore, this tool has particular advantages. As with the tool specifically covered by independent claim 55, the tool of claim 64 enables the prosthesis component to be cemented in place while it is accurately held in the desired position through the use of the tool.

Independent claim 65 sets forth another particular advantageous feature of the invention by stating that the tool having the elongated body and the head configured to cooperate with a prosthesis component also includes a first seal enabling the component to be releasably mounted to the tool by suction. Furthermore, the tool includes a second sealing component which is proximate to the head and inflatable. The inflatable seal element enables the tool to convey the component to the cement while pressurizing the cement to ensure that any bodily fluids are expelled from the region that is to be cemented. This particular feature of the invention ensures that a homogeneous cement mantel can be formed around the component.

With respect to the known prior art, it should be initially recognized that none of the cited art of record specifically discloses or suggests the advantages of the present invention as set forth above. With regard to the documents cited by the Examiner in the outstanding Office Action, Tronzo discloses a modified hip screw arrangement used to pin a fracture in a bone where osteoporosis exists. Referring to Figure 1 in this patent, hip screw 32 is placed inside a femur to pin a fracture 10. After the pin has been screwed into place, cement is then injected through the pin such that it surrounds some of the screw threads. The cement prevents the screw threads from cutting their way out of the

bone. Based on the above, it should be readily apparent that Tronzo relates to an apparatus for performing an entirely different procedure than the present invention, namely, pinning fractures, and does not relate to an apparatus for positioning a component of or for a prosthesis including a tool having structure according to that set forth in accordance with the present invention. Particularly, Tronzo does not disclose a tool which is capable of carrying or manipulating a component of or for a prosthesis, a cement delivery system in a tool which is used to carry and manipulate such a component, or any analogous type of inflatable seal arrangement.

Brown discloses an assembly for bolting a prosthesis component to a femur while it is being cemented in place. Referring to Figures 1 and 2, the assembly comprises a base guide 11 which is bolted to the femur. The prosthesis component is gripped between two holding plates 21 and 22 which are then bolted together and screwed to the base guide with the sealing plate 26 therebetween. Cement is injected into a bore around the prosthesis component through the holding plates and sealing plate. However, Brown does not disclose a tool as such but rather an arrangement of various components which must be assembled within an implant region in order to be fixed to a bone. Particularly, Brown does not disclose a tool for carrying and manipulating a prosthesis component or an inflatable seal for sealing a cavity or bone into which the component is to be implanted. Instead, the apparatus of Brown requires an extremely invasive procedure both to fix and remove the complex assembly from the body.

Rudischauser discloses an endoscope comprising an optical channel and a working channel for enabling minimally invasive surgery to be carried out while viewing the internal region which is being operated on. The working channel allows a surgeon to pass tools, such as dissecting forceps (see column 5, lines 62-65) into the body for performing the operation. The endoscope also comprises a channel for supplying and withdrawing irrigation fluids to cleanse the operation site. However, Rudischauser does not disclose or even suggest an apparatus suitable for positioning and cementing a component of or for a prosthesis. This document certainly does not disclose a tool

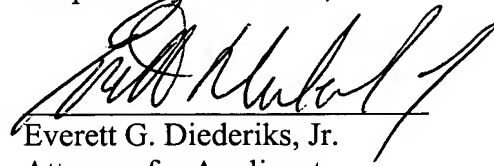
comprising an end portion having means for releasably mounting a prosthesis component, nor does it disclose an inflatable seal at this end portion for sealing a cavity or bore in a bone which is to be cemented. It must be realized that the Rudischauser tool constitutes an endoscope and therefore is an entirely different tool designed for entirely different purposes than that of the present invention. To this end, the tool of Rudischauser does not include a head portion configured to cooperate with a surface of a prosthesis component, let alone a seal arrangement corresponding to that set forth in independent claim 55 or the particular seal arrangements of the present claims, including the annular sealing element of claim 60 or the suction arrangements of claims 64 and 65.

Amstutz, also cited by the Examiner, does not disclose an analogous tool to that presently claimed. For example, Amstutz does not provide a tool having a cement delivery passage. Accordingly, the prior art tool cannot hold the component in place while cementing the component in a body. Instead, Amstutz delivers cement to an implant site before a component is positioned at the site. Therefore, the cement is delivered in an initial stage of a procedure and a tool then conveys a component to the cement. This arrangement is considered problematic as the cement may begin to cure before the component is properly inserted into the body.

As indicated above, the Applicant has presented all new claims in this application, without the introduction of any new matter, in order to more particularly point out and distinctly claim the invention verses the known prior art. Many of the dependent claims further distinguish the present invention from the known prior art. For instance, claim 57 further requires the tool to include a mating part that is engageable by the component and a locking means for releasably locking the component thereto. Claims 58 and 59 sets forth further specifics of the locking means, with claim 59 specifying that the locking means employs suction in a manner analogous to that discussed above. Corresponding locking structure is set forth in claims 61-63 as well. In any event, based on the above remarks and the amendments to the claims, reconsideration of the application is respectfully requested. If the Examiner should have any additional concerns regarding

the allowance of this application, he is cordially invited to contact the undersigned at the number provided below to further expedite the prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Everett G. Diederiks, Jr.", written over a horizontal line.

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